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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/091,912

03/05/2002

Richard R. Bott

GC724

9189

7590

05/18/2005

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,912

Applicant(s)

BOTT ET AL

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 19, 28, 30, 31 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 19, 28, 30, 31 and 33-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/2005 has been entered.

[2] Claims 1, 19, 28, 30-31, and 33-50 are pending in the application.

[3] Applicants' amendment to the claims, filed 3/15/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] Applicants' arguments filed 3/15/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

[6] Claims 1 and 28 are grammatically incorrect in the recitation of "the residue positions corresponding to sites" or "the residue positions corresponding to site" and it is

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suggested that the phrases be replaced with “the residue position corresponding to site.”

[7] Claims 28 and 30 are objected to in the recitation of “SEQ ID NO:-2” as this is an improper sequence identifier and should be replaced with, for example, “SEQ ID NO:2”.

Claim Rejections - 35 USC § 112, Second Paragraph

[8] Claims 1, 19, 28, 30-31, and 33-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 1 (claim(s) 19, 31, and 34-38 dependent therefrom), 28 (claim(s) 30 and 33 dependent therefrom), 39 (claim(s) 40-41, 44, and 46-50 dependent therefrom), and 42 (claim(s) 43 and 45 dependent therefrom) are indefinite in the recitation of “wild-type *Pseudomonas mendocina* cutinase” or “wild-type *P. mendocina* cutinase” as it is unclear from the claims and the specification as to the sequence of wild-type *Pseudomonas mendocina* cutinase such that a skilled artisan could compare the polyesterase activities and thermostabilities of the claimed cutinase variant and the wild-type cutinase. It is suggested that applicants clearly identify the intended wild-type *Pseudomonas mendocina* cutinase by a sequence identifier, i.e., “SEQ ID NO:”.

[b] Claim 19 is confusing in the recitation of “said variant comprises the substitutions: Met at position 192, and further comprising the substitutions of Val at position 194, and Ser at position 219.” The “wild-type” residues at positions 192, 194, and 219 are Ile, Phe, and Ser, respectively. Thus, the claim has been interpreted as a

cutinase having a Met at position 192 and a Val at position 194. However, there is no substitution of Ser as Ser is the original residue at position 219. It is suggested that applicants clarify the meaning of the claim.

[c] Claim 49 is confusing in the recitation of "said variant comprises the substitution of Asn at position 194." The paper copy of the sequence listing, filed 7/30/2002, indicates that Phe is at position 194, not Asn. Thus, it is unclear as to how the variant comprises substitution at position 194. It is suggested that applicants clarify the meaning of the claim.

Claim Rejections - 35 USC § 112, First Paragraph

[9] Claims 1, 19, 31, 34-41, 44, and 46-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

Amended claim 1 (claim(s) 19, 31, and 34-38 dependent therefrom) recites the limitation "variant has increased polyesterase activity and enhanced thermostability."

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The examiner can find no support for a cutinase variant having mutation at position 192 and having increased polyesterase activity and enhanced thermostability in the specification, claims, or drawings as originally filed. While applicants state, "the present Claims find more than sufficient support in the Specification as filed," this assertion does not constitute a showing of support for this limitation. Applicants are invited to show support for the recited limitation in accordance with MPEP § 2163.

Amended claim 39 (claim(s) 40-41, 44, and 46-50 dependent therefrom) recites the limitation "variant has increased polyesterase activity and enhanced thermostability." The examiner can find no support for a cutinase variant having mutation at position 194 and having increased polyesterase activity and enhanced thermostability in the specification, claims, or drawings as originally filed. While applicants state, "the present Claims find more than sufficient support in the Specification as filed," this assertion does not constitute a showing of support for this limitation. Applicants are invited to show support for the recited limitation in accordance with MPEP § 2163.

[10] The written description rejection of claims 1, 19, 28, 30-31, and 33-50 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and for the reasons stated below.

RESPONSE TO ARGUMENT: Beginning at the bottom of p. 7 of the response, applicants argue the written description rejection is overcome by amendment to recite specific substitutions at position 192 or 194 with an additional mutation or mutations.

Applicants' argument is not found persuasive. As noted in previous Office actions, the claims recite the transitional phrases "comprising substitution," "comprises

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the substitutions,” “comprises a substitution,” and “comprises the substitution” (see MPEP § 2111.03) and the claims have been broadly interpreted in accordance with MPEP § 2111 as meaning a cutinase comprising a substitution corresponding to the recited positions and comprising substitution at any other position(s) of the cutinase amino acid sequence. Thus, while the claims recite the specific mutation(s) at position(s) 192, 194, 192/194, or 192/194/219, the remaining sequence of the polypeptide is completely undefined. As previously noted, this interpretation is supported by the prosecution history and – it is particularly noted that – applicants do not dispute this interpretation. As such, the genus of claimed cutinases encompasses species that are widely variant with respect to their structures. While the cutinase variants are required to have the “common structural characteristic” of mutation at position 192, 194, 192/194, or 192/194/219, this “common structural characteristic” does not constitute a substantial portion of the genus. In view of the substantial variation among species of the genus and that the “common structural characteristic” does not constitute a substantial portion of the genus, the disclosed representative species of variants of SEQ ID NO:2, wherein a position or positions selected from 192, 194, 192/194, or 192/194/219 is/are mutated, fail to represent the entire genus of claimed cutinase variants. Consequently, the claimed genus of cutinase variants is not adequately described by the specification.

[11] The scope of enablement rejection of claim(s) 1, 19, 28, 30-31, and 33-50 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and for the reasons stated below.

RESPONSE TO ARGUMENT: Beginning at the middle of p. 8 of the response, applicants argue the scope of enablement rejection is overcome by amendment to recite specific substitutions at position 192 or 194 with an additional mutation or mutations.

Applicants' argument is not found persuasive. The examiner maintains the position that the specification, while being enabling for a variant of SEQ ID NO:2, wherein the variant is mutated at position(s) 192, 194, 192/194, or 192/194/219 of SEQ ID NO:2, does not reasonably provide enablement for the broad scope of claimed cutinase variants. There is no dispute that the claims recite particular sites of mutation corresponding to amino acids of SEQ ID NO:2. However, as noted above and in previous Office actions, the claims recite the transitional phrases "comprising substitution," "comprises the substitutions," "comprises a substitution," and "comprises the substitution" (see MPEP § 2111.03) and the claims have been broadly interpreted in accordance with MPEP § 2111 as meaning a cutinase comprising a substitution corresponding to the recited positions and comprising substitution at any other position(s) of the cutinase amino acid sequence. Thus, while the claims recite the specific mutation(s) at position(s) 192, 194, 192/194, or 192/194/219, the remaining sequence of the polypeptide is completely undefined. As previously noted, this interpretation is supported by the prosecution history and – it is particularly noted that – applicants do not dispute this interpretation. As such, the claims broadly encompass a vast number of cutinase variants without providing guidance regarding those variants that will likely exhibit the desired increased thermostability and optionally increased

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polyesterase activity. As previously noted (see pp. 12-13 of the Office action mailed 1/29/2004), and undisputed by applicants, without such guidance, it is highly unpredictable as to which mutation(s) in addition to positions 192, 194, 192/194, or 192/194/219 can be made with an expectation of maintaining the desired activity/utility. In view of the lack of guidance and working examples, trial and error experimentation is required to make the full scope of claimed variants, which was not routine at the time of the invention. As such, undue experimentation is required to make the full scope of cutinase variants broadly encompassed by the claims.

Claim Rejections - 35 USC § 103

[12] The rejection of claim(s) 1, 28, 30, 33-39, and 41-50 under 35 U.S.C. 103(a) as being unpatentable over Poulouse et al. (US Patent 5,352,594) is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Beginning at the bottom of p. 8 of the response, applicants argue the rejection has been overcome by amendment to limit the claimed cutinase variants to those that exhibit increased polyesterase activity and enhanced thermostability as compared to a wild-type *P. mendocina* cutinase.

Applicants' argument is not found persuasive. It is noted that, while applicants assert "The Claims are Unobvious," applicants do not dispute the examiner's assertion that, in view of the teachings of Poulouse et al., the claimed cutinase variants would have been obvious to one of ordinary skill in the art at the time of the invention. In this case, applicants make no attempt to distinguish the claimed invention from the cutinase

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variants of the prior art. Instead, applicants merely state that they have “amended the Claims to recite that the cutinase variants exhibit increased polyesterase activity and enhanced thermostability.” Presumably, the implication is that the cutinase variants as suggested by Poulouse et al. would not have the recited activity or activities. As noted in a previous Office action, it is acknowledged that the teachings of Poulouse et al. do not appear to have been directed to achieving cutinase variants having increased thermostability and optionally increased polyesterase activity. However, MPEP § 2144 makes clear that “[i]t is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.” Poulouse et al. clearly suggest making the claimed cutinase variants, which is undisputed by applicants, and the resulting cutinase variants would inherently have the recited activity or activities, which again is undisputed by applicants. At least for these reasons, the claimed cutinase variants would have been obvious to one of ordinary skill in the art at the time of the invention.

Citation of Relevant Prior Art

[13] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Okkels et al. (US Patent 6,156,552) teaches variants of Pseudomonas sp. Strain SD 705. Okkels et al. teaches specific mutants of this cutinase including mutation at position 178, 180, 192, and 205 (columns 1 and 3). However, a visual inspection of the sequence of the cutinase of Okkels et al. indicates that the residues at positions 178, 180, 192, and 205 do not correspond to amino acids 178,

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180, 192, and 205 of SEQ ID NO:2. In fact, the two sequences (the cutinase of Okkels and the cutinase of SEQ ID NO:2) do not appear to be closely related. Thus, while one of ordinary skill in the art would clearly have the ability and motivation to make the mutant cutinases of Okkels et al., there is no reasonable expectation that these mutants would have increased thermostability and optionally increased polyesterase activity. Furthermore, as the sequence of the cutinase of Okkels et al. is not closely related to the cutinase of SEQ ID NO:2, particularly at the positions corresponding to amino acids 192, 194, and 219 of SEQ ID NO:2), that the mutants of Okkels et al. would have increased thermostability and optionally increased polyesterase activity it is not necessarily an inherent characteristic. As such, it is the examiner's position that the reference of Okkels et al. cannot be used as prior art under either 35 U.S.C. 102 or 35 U.S.C. 103.

Conclusion

[14] Status of the claims:

- Claims 1, 19, 28, 30-31, and 33-50 are pending.
- Claims 1, 19, 28, 30-31, and 33-50 are rejected.
- No claim is in condition for allowance.

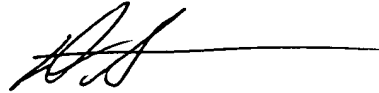
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or

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proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be 'DJS', is written over a horizontal line.

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER